



Kentucky Board of Pharmacy

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What Does USP Chapter <797> Mean?

Submitted by Alex Bertram, PharmD Candidate

As of January 1, 2004, it is required, in order to be compliant with KRS 217.055, that all compounding personnel follow guidelines set forth in United States Pharmacopeia (USP) General Tests and Assays Chapter <797>, Pharmaceutical Compounding—Sterile Preparations. So what does this mean for persons who compound sterile preparations? This article shall explore some, but not all, of the requirements needed in order to comply.

USP Chapter <797> is intended to prevent harm to patients receiving compounded sterile preparations (CSP) as well as increase the scope of coverage of these regulations to all

personnel who compound. In order for sterile compounding to occur, a few criteria will have to be met; cleaner facilities, specific training and testing of personnel in aseptic technique, air quality evaluation and maintenance, knowledge of sterilization, and solution stability principles and practices. No longer do these guidelines apply for just pharmacists, but for all personnel compounding sterile preparations.

Microbial contamination risk levels are classified into low, medium, and high (as defined in USP <797>, refer to *Table 1* below for examples of low-, medium-, and high-risk compounding) CSPs. All CSP areas require an International Organization for Standardization (ISO) Class 5 or better air

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Table 1

Risk Classification	Example
Low	<ol style="list-style-type: none"> 1. Single transfer of sterile dosage forms using sterile syringes with sterile needles. 2. Manually measuring and mixing no more than three manufactured products to compound drug admixtures and nutritional solutions.
Medium	<ol style="list-style-type: none"> 1. Compounding of total parenteral nutrition fluids using manual or automated devices during which there are multiple injections, detachments, and attachments of nutrient source products to the device or machine to deliver all nutritional components to a final sterile container. 2. Filling of reservoirs of injection and infusion devices with multiple sterile drug products and evacuation of air from those reservoirs before the filled device is dispensed. 3. Filling of reservoirs of injection and infusion devices with volumes of sterile drug solutions that will be administered over several days at ambient temperatures between 25° C and 40° C. 4. Transfer of volumes from multiple ampuls or vials into a single, final sterile container or product.
High	<ol style="list-style-type: none"> 1. Dissolving non-sterile bulk drug and nutrient powders to make solutions, which will be terminally sterilized. 2. Sterile ingredients, components, devices, and mixtures that are exposed to air quality inferior to ISO Class 5. This includes storage in environments inferior to ISO Class 5 of opened or partially used packages of manufactured sterile products that lack anti-microbial preservatives. 3. Measuring and mixing sterile ingredients in non-sterile devices before sterilization is performed. 4. Assuming, without appropriate evidence or direct determination, that packages of bulk ingredients contain at least 95% by weight of their active chemical moiety and have not been contaminated or adulterated between uses.



FDA Issues Final Rule Prohibiting the Sale of Ephedra Supplements

On February 6, 2004, Food and Drug Administration (FDA) announced the issuance of a final rule prohibiting the sale of dietary supplements containing ephedrine alkaloids (ephedra).

At the end of last year, FDA issued letters to manufacturers who market ephedra-containing supplements, informing them of the upcoming rule. FDA also urged consumers to stop using ephedra-containing dietary supplements immediately. Studies show that ephedra-containing dietary supplement have adverse effects on the cardiovascular and central nervous systems including high blood pressure, heart palpitations, tachycardia, stroke, and seizures. FDA has linked at least 155 deaths with the use of dietary supplements containing ephedra.

For more information, including a Web link to the final rule, visit the following Web site: www.fda.gov/bbs/topics/NEWS/2004/NEW01021.html.

The final rule became enforceable on April 12, 2004. California, Illinois, and New York were the first states to ban the sale of ephedra.

DEA Issues Clarification of the Exemption of Sales of Pseudoephedrine and Phenylpropanolamine

In attempts to clarify existing laws and regulations regarding the over-the-counter (OTC) sale of pseudoephedrine and phenylpropanolamine, Drug Enforcement Administration (DEA) issued an interpretive rule this past January. This interpretive rule does not change any of DEA's regulations, nor will it have an impact on individual retail customers of such products who have been purchasing them from retailers that have been properly following DEA's regulations.

Specifically, the interpretive rule emphasizes that sales transactions of ordinary OTC pseudoephedrine and phenylpropanolamine products ("safe harbor" products) are exempt from being regulated transactions as long as each transaction is below the 9-gram threshold to an individual for legitimate medical use. Apparently, some retail distributors have misinterpreted current DEA regulations and believe that they may sell as much "safe harbor" pseudoephedrine and phenylpropanolamine to any person for any purpose as often as that person wishes to make a purchase. The DEA interpretive rule clearly dispels that belief.

Currently, retail distributors of ordinary OTC pseudoephedrine and phenylpropanolamine products are exempt from registering with DEA as a distributor of List I chemicals and complying with the record keeping and other regulatory requirements as long as individual transactions for legitimate personal medical use remain below the 9-gram threshold (in packages of not more than 3 grams).

To obtain more information, please visit DEA's Diversion Control Program Web site, www.DEAdiversion.usdoj.gov.

Note: Although most products containing phenylpropanolamine were discontinued pursuant to the action of FDA in November 2000, there remains some legitimate veterinary uses for phenylpropanolamine that will ensure some level of its continued production and availability. Therefore, these products are subject to the existing DEA regulations and this interpretive rule.

DEA Introduces Pharmacy Theft Prevention Program

In response to increasing theft and armed robberies against pharmacies, DEA's Office of Diversion Control has introduced the Pharmacy Theft Prevention Program. The program is based on a previous initiative that was developed during the late 1970s and early 1980s when there was a similar unprecedented spike in the occurrence of thefts and robberies against pharmacies.

The intent of the program is to provide education and increased communication to pharmacists and pharmacy staff to prevent pharmacy theft. The program includes collaboration with and participation from law enforcement, regulators including state pharmacy boards, state and federal prosecutors, the media, and the public along with the pharmacy community. The Pharmacy Theft Prevention Program will also provide a means to maximize the use of limited resources available to law enforcement to address, minimize, and eliminate pharmacy thefts in areas that experience such problems.

Staff members of the DEA's Office of Diversion Control have begun a series of regional meetings to promote the program to DEA Diversion field elements, state pharmacy boards, and local pharmacy associations. To implement the program in your community, or to obtain more information regarding the program and its operation, call DEA Headquarters, Office of Diversion Control, Liaison and Policy Section, at 202/307-7297.

Concentrated Morphine Solutions and Serious Medication Errors

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (USP) and FDA in analyzing medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site (www.ismp.org) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 1800 Byberry Rd, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.



According to a recent newspaper report, a 91-year-old man being treated for a mild heart attack was mistakenly given a 100-mg dose of ROXANOL™ (concentrated morphine solution) instead of 5 mg as prescribed. The error may have contributed to the patient's death the following day. Last fall, Elan Pharmaceuticals (the manufacturer of Roxanol at the time; aaiPharma recently acquired the product from Elan) issued a safety alert warning about deaths from accidental overdoses (www.fda.gov/medwatch/SAFETY/2003/roxanol.htm). Most overdoses involved morphine solutions that were mistakenly ordered, dispensed, and labeled by volume (mL), not milligrams. For example, in some cases, patients received 5 mL of



Roxanol 20 mg/mL (100 mg) instead of the prescribed 5 mg. The newspaper report did not describe how this most recent error happened; however, it mentioned that Roxanol 100 mg had been given instead of 5 mg, pointing once again to the scenario described in the recent safety alert from Elan.

Several manufacturers distribute morphine solution in different formulations, primarily labeled (and listed in drug references) in mg/mL (eg, 20 mg/mL) or mg/5 mL (eg, 100 mg/5 mL, 20 mg/5 mL). When concentrated morphine is stored in pharmacies or in patient care areas in hospitals or long-term care facilities, it is often kept next to conventional concentrations. Thus, it is easy to confuse these products and dosage strengths. Also, some physicians have prescribed the medication in terms of mL instead of mg, which has led to errors because multiple concentrations exist. Because we continue to hear about these tragic overdoses, we make these recommendations to reduce the risk of errors with concentrated morphine products:

- ◆ If you consult with nursing homes or hospitals, avoid stocking concentrated morphine solutions in patient units when possible, including the emergency department. Keep in mind that the drug is used primarily to treat chronic pain.
- ◆ Dispense concentrated solutions only when ordered for specific patients who require higher-than-usual doses due to severe chronic pain.
- ◆ Affix an auxiliary label to the morphine concentrate bottle to warn about its high concentration and segregate the solution from the other concentrations.
- ◆ Working with local physicians, purchase and dispense concentrated solutions in dropper bottles (available from at least two manufacturers) to help prevent dose measurement errors and differentiate the concentrated product from the conventional products. For patients in hospitals or long-term care, dispense concentrated solutions in unit doses whenever possible.
- ◆ Educate others to never prescribe or dispense liquid medications without the dose specified in milligrams.
- ◆ Educate staff about the risk of morphine errors and develop guidelines to promote its safe use.
- ◆ Manufacturers should standardize the way strength is expressed on labels, preferably in terms of mg/mL for all forms. This would improve clarity when comparing product labels (eg, it is easier to differentiate 4 mg/mL and 20 mg/mL; harder to differentiate 20 mg/mL and 20 mg/5 mL).

Finally, we disagree with Elan's suggestion in its recent safety alert for prescribers to include the desired concentration of morphine along with the patient's dose in milligrams and the corresponding volume (eg, Roxanol 10 mg/5 mL, give 10 mg [5 mL] prn pain). Listing the desired concentration could actually lead to confusion and errors. If the prescribed concentration is not available and a different concentration is substituted, the prescriber's directions regarding the volume to administer would no longer apply. Yet, if these directions remain on a medication administration record, or a prescription bottle, the wrong dose could be administered.

NABP Releases Updated Model Rules for the Licensure of Wholesale Distributors

On February 20, 2004, the National Association of Boards of Pharmacy® (NABP®) released the updated Model Rules for the Licensure of Wholesale Distributors. The updated Model Rules, part of the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy*, were provided to assist state boards of pharmacy in maintaining the integrity of the US medication distribution system through the regulation of wholesale distributors. The updated Model Rules are the result of a concerted effort between NABP and other representatives from pharmacy, government, and the wholesale distributor industry to protect the public from the ill effects of counterfeit drugs and devices.

In addition to stricter licensing requirements such as criminal background checks and due diligence procedures prior to wholesale distribution transactions, the Model Rules mandate specific drug pedigree requirements for products that are particularly prone to adulteration, counterfeiting, or diversion. These products, as defined in the updated Model Rules, are designated as the "National Specified List of Susceptible Products." Also, the updated Model Rules introduce the position of "Designated Representative." The "Designated Representative" of a wholesale distributor is the person who is actively involved in and aware of the actual daily operation of the Wholesale Distributor.

The Model Rules for the Licensure of Wholesale Distributors along with the National Specified List of Susceptible Products can be downloaded from NABP's Web site, www.nabp.net.

New Bar Code Requirements Aim to Reduce Risk of Medication Errors

In late February, FDA issued the final rule Bar Code Label Requirements for Human Drug Products and Biological Products. This final rule requires the inclusion of linear bar codes on most prescription drugs and certain OTC drugs. Each bar code must, at minimum, contain the drug's National Drug Code number, but companies are encouraged to include additional information such as the product's lot number and expiration date. For blood and blood products used in a transfusion, the final rule also requires the use of machine-readable information in a format approved for use by FDA. The machine-readable information must include, at a minimum, the facility identifier, the lot number relating to the donor, the product code, and information on the donor blood type.

FDA is hoping that the bar code rule will encourage the widespread adoption of advanced information systems that, in some institutions, have reduced medication errors by 85%.

FDA expects that, with full implementation, the linear bar codes will result in more than 500,000 fewer adverse events over the next 20 years and a 50% reduction in medication errors that would otherwise have occurred upon dispensing or administration. New medications covered by the rule must comply within 60 days of their approval and previously approved medications and blood/blood products must comply within two years.

More information including a link to the final rule is available on FDA's Web site at www.fda.gov/oc/initiatives/barcode-sadr.

Table 2

Risk Level	Room Temperature	Refrigeration	Freezer (<20 °C)
Low	48 hours	14 days	45 days
Medium	30 hours	7 days	45 days
High	24 hours	3 days	45 days

quality, either with a Laminar airflow workbench (LAFW) or a well-designed positive pressure barrier isolator, in order to aseptically compound sterile preparations. The clean room includes an anteroom area and a buffer room/zone. Buffer room/zone air for all risk levels must meet ISO Class 8 qualifications. The anteroom area can contain supplies, such as needles, syringes, ampuls, bags, vials of parenteral fluids, and packages of transfer tubing sets for large-volume fluids that are uncartoned and disinfected. The anteroom area and buffer room/zone must be separated by a line of demarcation for low and medium risk levels. For high risk level, they must be separate rooms.

Beyond-use dating is also a new term described by USP <797>, and was formerly known as expiration dating. Two factors that play into beyond-use dating are chemical stability and sterility. Sterility by definition is the absence of viable microorganisms. A CSP is either sterile or not sterile. USP <797> defines the published limits of sterility (*Table 2*, above) and this may not be exceeded unless testing is performed for the CSP. If sterility testing is performed according to USP <71> Sterility Tests, the CSP can be assigned beyond-use dating based on the maximum chemical stability of the drug in solution as permitted by valid references.

Proper hand sanitizing and gowning activities must occur before entering the buffer room/zone each time. Gowning activities include removal of outer lab jackets or the like, makeup, and jewelry. Thorough scrubbing of hands and arms to the elbow is then conducted. After drying hands and arms, clean, non-shedding uniform components including hair covers, shoe covers, knee-length coats or coveralls, and appropriate protective gloves (in that order) should be donned. Coats should fit snugly at the wrists and be zipped or snapped closed in the front. Facemasks should be donned just before beginning activities in the direct contiguous compounding area to minimize airborne contaminants from coughing, sneezing, and talking. If a vertical flow LAFW, with a transparent shield between the face of the operator and sterile components, or barrier isolator is used, wearing of a facemask is optional. If the operator is to leave the buffer room/zone at any time, the coat may be carefully removed at the entrance and hung inside-out for re-donning upon re-entry, but only during the same shift. However, hair covers, masks, shoe covers, and gloves should be discarded and new ones donned prior to re-entry.

Clean room environments should be designed to have the cleanest work surfaces located in the buffer room/zone.

Only furniture, supplies, and other goods required for the tasks to be performed may be brought into the clean room, and they should be nonpermeable and non-shedding. The surfaces of ceilings, walls, floors, fixtures, shelving, counters,

and cabinets in the buffer room/zone should be smooth, impervious, free from cracks and crevices, and non-shedding, thereby promoting cleanability and minimizing spaces in which microorganisms and other contaminants may accumulate. Surfaces should be resistant to damage by sanitizing agents. Junctures of ceilings to walls should be covered or caulked to avoid cracks and crevices where dirt can accumulate. If ceilings consist of inlaid panels, the panels should be hydrophobic, and they should be caulked around each perimeter to seal them to the support frame. Preferably, floors should be overlaid with wide sheet vinyl flooring with heat-welded seams and coving at the sidewall. The buffer room/zone should contain no sinks or floor drains. Carts should be stainless steel or molded plastic, so that they are readily cleanable and sanitizable. The anteroom area should contain a hands-free sink for hand sanitizing.

Quality assurance practices include supervision of personnel compounding practices; annual media-fills (proper media-testing is defined in USP <797>) for personnel; written policies and procedures with personnel responsibilities spelled out; review of orders and packages of ingredients to assure correct identity and amounts of ingredients; and visual inspection of CSP. Special training should occur in order for personnel to comply with set forth guidelines. Environmental monitoring with certification of LAFW and barrier isolators every six (6) months, certification of the buffer room/zone and anteroom area every six (6) months, and bacterial monitoring using appropriate methods should be done at least monthly.

USP <797> was revised and renumbered in order to minimize the risk of contamination so patients can be treated as safely as possible. There is no doubt a serious issue of risk-to-benefit ratio and cost-effectiveness. However, patient safety should remain our focus, and if we can decrease the risk of contamination, we should. The Kentucky Board of Pharmacy realizes that many changes will have to be made for compliance and these changes will take time and money. But, an action plan should be constructed immediately for all persons responsible for compounding sterile preparations.

Continuing Education Reminder

The end of the year is fast approaching, and successful completion of the continuing education (CE) requirements is critical to this process. Pharmacists must complete fifteen (15) hours each year. All courses shall be Kentucky Board of Pharmacy or Accreditation Council for Pharmacy Education

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approved. Courses that have pending approval should not automatically be accepted as proof of completion. Pharmacists must have in their possession proof of successful completion of CE by December 31, 2004.

If you attend a live CE program, the completion date and the credit date for the program is the day that you were in attendance. If you participated in a home study program, these programs are not considered complete until you are awarded a certificate of completion from the provider with a dated certifying signature. Credit for the home study program is awarded on the date specified on the certificate, not the date you completed the CE and submitted it for grading.

Return of Repackaged Drugs

According to the Cabinet for Family and Health Services, Drug Enforcement Branch, through its regulation found at 902 KAR 55:065, an **acute care hospital pharmacy** that repackages drugs into unit-of-use containers may accept the return of that prescription drug and permit the returned drug to be redispensed **if** the packaging meets USP standards; the labeling and packaging has not been altered or defaced; the identity of the drug, its potency, lot number, and expiration date are legible; and the drug has not reached its expiration date.

In a **long-term care facility**, the dispensed unit-of-use container may be accepted for return when the packaging meets USP standards and it is sealed and tamper proof; the labeling and packaging has not been altered or defaced; the identity of the drug, its potency, lot number, and expiration date are legible; the drug has not been in the possession of the resident; the drug is not a controlled substance; and the drug has not reached its expiration date.

In an **outpatient (ambulatory) pharmacy**, the dispensed unit-of-use container must meet all of the requirements for the long-term care facility **AND** the drug must not require refrigeration, and less than 14 days must have elapsed since the drug was dispensed.

Pharmacists are encouraged to consider the dispensed drug's nature and the container's characteristics when making decisions concerning the return of dispensed drugs. Pharmacists should note that the regulation does not require a pharmacist to accept the return of dispensed drugs, nor, if accepted, to dispense the drug to another patient. Questions concerning this regulation's application to your practice should be directed to the Drug Enforcement Branch at 502/564-7985.

Pharmacist Recovery Network

Submitted by Katie Busroe, Pharmacy and Drug Inspector

The Kentucky Board of Pharmacy provided me with the opportunity to attend the University of Utah School on Alcoholism and Other Drug Dependencies, June 20-25, 2004. I arrived late the second evening of the School and met my

suitemate on her way to supper. After brief introductions, she asked if I was an addict. I did a quick mental debate while dragging out the word "nooooooo." "If I tell her I am with a regulatory agency is she going to lock me out of the suite or short sheet my bed? Wonder what kind of deal I can get on a return flight to Lexington tonight?" Fortunately, she, like everyone at the School, was extremely welcoming, accommodating, and kind. All were patient with me, answering my many questions without condescension.

This was the 53rd Annual Session of the University of Utah School on Alcoholism and Other Drug Dependencies. The School is divided into approximately 15 groups including various health care professions as well as women's issues, relapse prevention counseling, and American Indian sections. There were three general meetings of the entire School, but most of the week is spent with your particular section. Out of 500 attendees, 200 were in the pharmacy section, consisting of 100 practitioners and 100 pharmacy school students. Sessions were conducted throughout the day with open 12-step meetings every night.

I have been an employee of the Kentucky Board of Pharmacy for six years and a significant part of my job involves following impaired pharmacists. When impaired pharmacists appeared before the Board to petition for reinstatement of their licenses, I thought I was fairly open-minded. Often I doubted their sincerity. After all, they say the same thing; all their answers sound rehearsed. The Board frequently asked the question, "What is the first thing you think of when you wake up in the morning?" The answer was always, "To take one day at a time." I thought it a little too coincidental that everyone woke up thinking the same phrase. I did not know that "one day at a time" is a main theme for staying sober. Every impaired pharmacist spoke about his or her disease and I was almost insulted by this terminology. How can they compare their experience to cancer? However, after attending a session on the pathophysiology of addiction, I can now better understand. Originally, I thought I was allowed to attend the School because it was my turn to attend an out-of-state conference, but now I think it was because I had so far to come in my attitude toward addiction.

Before I attended the School I read the book *Alcoholics Anonymous*. I was surprised at how much it applied to me. I was not dealing with addiction to alcohol, nor was anyone in my immediate family. I did not expect to be able to relate to the 12 steps. As I read, it slowly began to dawn on me that the 12 steps are a solid foundation on how each of us should live our lives, regardless if you are dealing with an addiction or not. My summary of the 12 steps are:

- ◆ admit that you, alone, are powerless over some aspects of your life;
- ◆ believe in God or a Higher Power and turn your life over to God or your Higher Power;

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- ◆ take a moral inventory of yourself;
- ◆ admit to yourself, God or your Higher Power, and others the exact nature of your wrongs discovered from your moral inventory;
- ◆ be ready to have God or your Higher Power remove the defects of character discovered during your moral inventory and then ask God or your Higher Power to remove these;
- ◆ make a list of all those you have harmed and try to make amends when appropriate;
- ◆ do this continually in your life;
- ◆ seek to improve your conscious contact with God or your Higher Power through prayer and meditation, praying only for the knowledge of His will for you and the power to carry out His will;
- ◆ and, finally, help others.

Since attending the School, I have made an effort to follow the 12 steps in my life. I have discovered it is very difficult and I continually fail, but it can also be very rewarding.

I had not thought much about the School before attending and was more excited about going to Utah than I was focused on the meeting. In the airplane, I decided I would attend the sessions, but I did not want to get emotionally involved. I was really just looking forward to a break from my normal work routine. I soon discovered that I was unprepared for the week ahead. There were times I felt extremely uncomfortable. We attended a therapy session of a group from The Haven, a residential drug rehab center in Salt Lake City, UT. During the group therapy session, I felt as if I was invading other people's lives, hearing very personal emotions expressed in front of 200 strangers. I expected the entire meeting to be grave and was surprised at the sense of humor consistently conveyed in the sessions. It was astonishing for me that the people I

met, the recovering addicts, were easy to talk to, hilariously funny, and seemingly the most well-adjusted, content people I have encountered.

In Kentucky we are extremely lucky to have Brian Fingerson working tirelessly with impaired pharmacists. Mr Fingerson, with the support of the Kentucky Board of Pharmacy, has developed a strong recovery program. Should you, a pharmacist, or pharmacy school student you know need confidential help, please contact Mr Fingerson at 502/749-8385 or kyprn@insightbb.com.

Levothyroxine Substitution

The Board has received numerous inquiries about the legal substitution of various Levothyroxine products over the past few weeks. Generic substitutions must meet the requirements of KRS 217.822 and 201 KAR2:116. The main confusion started when several pharmacies were told by their employers that Synthroid® had been rated "AB" by Food and Drug Administration (FDA). When the Board tried to verify this with FDA, we did not receive official clarification from FDA until August 4, 2004. Therefore, until this time, any substitution of Synthroid was not allowable under Kentucky law since it was still considered a "BX"-rated product. Pharmacists can consult FDA's Web site (www.fda.gov) to ascertain the "Orange Book" rating of products and it is advised that you do this prior to contacting the Board Office.

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